

## US Institute of Medicine calls for changes at FDA

The US Institute of Medicine last week called for fundamental changes to the country's Food and Drug Administration to improve drug safety. Its report says that the agency should be funded better and that a greater emphasis on post-marketing surveillance is needed.

The report also calls for the FDA's culture and management and its system of funding to be changed. Some of the agency's income comes from user fees paid by drug companies.

It says, "Recent drug safety events have called into question FDA's regulatory decision making and oversight processes, and caused the public to question its ability to accomplish a balanced evaluation of safety and efficacy of the drugs it reviews and, after their approval, of their performance under real life conditions."

The centre is "excessively oriented toward supporting speed of approval and insufficiently attentive to safety," the report says.

Janice Hopkins Tanne *New York*

*The Future of Drug Safety: Promoting and Protecting the Health of the Public* is available at <http://national-academies.org>.

## Iraqi hospitals prove unwilling to treat soldiers

Iraq's Ministry of Health has obstructed access to care for injured members of the Iraqi armed services, a new report says.

Politics, lack of leadership, and a cultural bias against treating soldiers in civilian hospitals have hindered access to care for wounded members of Iraq's armed forces, says the article, which was published online on 19 September in the *World Journal of Surgery* ([www.springerlink.com](http://www.springerlink.com), doi: 10.1007/s00268-006-0203-5).

Many of the wounded soldiers, it says, are being treated by American doctors. "US surgeons are providing trauma care for Iraqi soldiers in American field hospi-

tals, with more than 80% of hospital bed days occupied by Iraqis."

The authors say it is imperative that the new Iraqi government and the international surgical community endorse the implementation of a single healthcare system for all Iraqis.

"Medical support for Iraqi security forces is facing major challenges that may limit the effectiveness of military and police units in conducting operations and could impede the ability of Coalition Forces to begin withdrawing personnel in 2006," write the authors.

Roger Dobson *Abergavenny*

## Guidelines on drug trials in children go out for consultation

Draft guidelines on the ethics of clinical trials involving children have been put out for public consultation by the European Commission and the European Medicines Agency.

The guidelines have been drawn up in line with EU legislation on the conduct of good clinical practice in trials of medicinal products for human use. This legislation specifically called for criteria to be agreed to protect children.

The guidelines are directed at sponsors of clinical trials, ethics committees, and investigators of clinical trials involving children of all ages (from birth to 18 years of age). They emphasise that trials should be carried out under conditions that provide the best possible protection for this vulnerable population, while recognising that children have the right to benefit from research.

The guidelines set out the criteria that those conducting trials must follow when seeking the informed consent of parents or legal representatives and, depending on their maturity, the assent of children themselves. Consent should always be obtained before potential participants in a trial are approached, and separate forms for children should be used that provide age appropriate information.

Rory Watson *Brussels*

The draft guidelines will be available soon at <http://emea.europa.eu>.

## FDA warns US consumers not to eat spinach after *E coli* outbreak

Fred Charatan *Florida*

An outbreak of *Escherichia coli* O157:H7 in the United States that began in August has now spread to 25 states and made 171 people sick.

In the worst affected state, Wisconsin, a 77 year old woman died from the haemolytic-uraemic syndrome. Two other suspicious deaths are being investigated: a child in Idaho and an elderly woman in Maryland, who had both eaten raw spinach before falling sick.

Half of the people infected have been admitted to hospital, 27 with the haemolytic-uraemic syndrome. About 80% of the infected people reported that they had eaten spinach, and health officials believe that transmission was through raw spinach, contaminated by human or animal waste or irrigation water.

The Food and Drug Administration said that the first cases occurred on 23 August. The FDA is working with the Centers for Disease Control and Prevention, which has set up an emergency operations centre in Atlanta to help state agencies in testing for *E coli*.

The widespread transmission indicates early contamination of the spinach crop, mainly in California's Salinas Valley, the self styled "salad bowl to the world."

New Mexico's public health laboratory made a breakthrough by isolating *E coli* from an opened package of spinach that came from the refrigerator of a person who ate some of it before

becoming sick. All *E coli* O157:H7 bacteria associated with the outbreak have the same DNA pattern, including the strain isolated in New Mexico.

"I expect we will continue to see cases for the next few days," said David Acheson, chief medical officer for the FDA's Center for Food Safety and Applied Nutrition, on 19 September. "One possibility is that this is a virulent strain," he added.

The FDA has issued several warnings to growers in the past regarding the control of crop contamination. It published its *Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption* in October 2004.

*E coli* O157:H7 was first recognised in the US in 1982. Since 1995 the US has experienced 20 outbreaks, mostly in the Salinas Valley.

"In light of continuing outbreaks, it is clear more needs to be done," wrote Robert Brackett, director of the Center for Food Safety and Applied Nutrition, in a letter to growers on 4 November 2005. The FDA has sent inspectors to the current suspect California farms, seeking primary transmission sites of the outbreak.

In response to the FDA's warning two major spinach growers have withdrawn their product and ploughed their crops in, while supermarkets nationwide have stripped their shelves of all spinach products. □

More information is at [www.fda.gov](http://www.fda.gov).



Don Moseley, an employee of General Produce, opens cases of bagged spinach and tosses them into a skip in Forest Park, Georgia